



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: February 4, 1999

TO: Sadye Dunn, Secretary

FROM: Jeffrey S. Bromme 
General Counsel

SUBJECT: December 16, 1998 OGC Memorandum Regarding
"Substantial Compliance"

There have been a number of requests from the public for the December 16, 1998 Office of General Counsel memorandum entitled "Bunk Beds -- Notice of Proposed Rulemaking -- Legal Memorandum." As you know, we ordinarily do not release OGC memoranda to the public on various confidentiality grounds. In this case, however, the essence of our legal advice to the Commission regarding the meaning of "substantial compliance" is already public. For example, we have expressed our conclusions and advice orally in open meetings, and the Federal Register notice announcing the proposed rule summarizes our view of "substantial compliance." Moreover, because the Commission has determined to seek public comment on the issue of "substantial compliance," its deliberations on the final bunk bed rule may well be enhanced if the public has an opportunity to review the bases for the OGC conclusions and comment upon them. Consequently, we have determined that most of Section IV of the memorandum, which addresses "substantial compliance," will be added to the record.

A copy of our memorandum, appropriately redacted, is attached for the record. By adding this memorandum to the record, OGC does not waive the Commission's right to prevent disclosure of other OGC memoranda, where withholding the memoranda is permitted by law.

Attachment

cc w/out attachment:

Chairman Ann Brown
Commissioner Mary Sheila Gall
Commissioner Thomas Moore

CPSA 6 (b)(1) Cleared
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CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

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MEMORANDUM

DATE: DEC 16 1998

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey S. Bromme, General Counsel *[Signature]*
Harleigh Ewell, Attorney, GCRA (Ext. 2217) *[Signature]*

SUBJECT: Bunk Beds--Notice of Proposed Rulemaking--Legal Memorandum

REDACTED

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No Mfrs/Prvt. Bns. or
Products Identified
[Signature]
Firms Notified
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NOTE: This document has not been reviewed or accepted by the Commission
Initial rh Date 12/16/98

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IV. The Impact of the Existing Voluntary Standard on the Commission's Authority to Propose This Rule.

Section 9(f)(3)(D) of the CPSA and Section 3(i)(2) of the FHSA apply here. Section 9(f)(3)(D) of the CPSA provides:

The Commission shall not promulgate a consumer product safety rule unless it finds (and includes such finding in the regulation) --

* * * * *

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(D) in the case of a rule which relates to a risk of injury with respect to which persons who would be subject to such rule have adopted and implemented a voluntary standard, that --

(i) compliance with such voluntary standard is not likely to result in the elimination or adequate reduction of such risk of injury; or

(ii) it is unlikely that there will be substantial compliance with such voluntary standard

The operative language of FHSA Section 3(i)(2) is the same.

Congress added this language to the CPSA in 1981. Omnibus Budget Reconciliation Act of 1981, Section 1203, Pub. L. 97-35, 95 Stat. 703. That legislation also amended the FHSA and FFA to require the Commission to defer to voluntary standards unless it finds that compliance with the voluntary standard would not likely result "in the elimination or adequate reduction of [the] risk of injury" or that there would not be "substantial compliance" with the voluntary standard. See CPSA § 7(b)(1); FHSA § 3(i)(2); FFA § 4(j)(2). Congress added similar language with respect to denial of petitions in 1990.^{2/}

A. The Voluntary Standard Is Not Substantively Adequate.

As explained in the staff's briefing package, the draft proposed rule goes beyond the provisions of the ASTM voluntary standard. It eliminates the voluntary standard's option to have an opening of up to 15 inches at each end of the wall-side guardrail, and it extends the upper boundary of the entrapment protection for the lower bunk end structures from 9 inches above the upper surface of the lower bunk's mattress to just below the level of the underside of the upper bunk foundation. Both of the provisions that are in the draft proposed rule but not in the voluntary standard address fatalities and, as noted, have benefits that bear a reasonable relationship to their costs. Therefore, OGC concludes that the Commission could find that compliance with the voluntary standard would not be likely to result in the elimination or adequate reduction of the risk of entrapment injury or death. In that event, the voluntary standard would not bar the proposed rule even if there were

^{2/} See FHSA § 3(j); CPSA § 9(i); FFA § 4(k). Consumer Product Safety Improvement Act of 1990, Section 110, Pub. L. 101-608, 104 Stat. 3110.

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"substantial compliance" with the standard. As a technical legal matter, therefore, this finding would make it unnecessary to reach the "substantial compliance" finding. However, as discussed in the remainder of this memorandum, even if the ASTM standard were substantively adequate, it is our opinion that the Commission can find that it is not substantially complied with.

B. The Commission Can Conclude That Substantial Compliance with the ASTM Standard Does Not Exist.

OGC has extensively researched and analyzed the question of "substantial compliance" in an effort to articulate a test for determining whether such compliance exists. We have examined past instances when the Commission has considered this and related questions. We also have examined the statutory language and structure, as well as the legislative history. Except through an examination of its structure, the statute does not define "substantial compliance," and the legislative history does not fully occupy the interstices left by the statute. No court has ever construed the language.

In the absence of clear and definitive guidance from Congress -- embodied in the statute's language -- the Commission has a generous degree of discretion in making its "substantial compliance" finding.^{3/} So long as the Commission can point to some rational basis in the record for concluding that it is "unlikely" there is "substantial compliance" with a voluntary standard, a court is likely to uphold that finding.

Based on the analysis that follows, it is our opinion that, when determining whether there has been or will be "substantial compliance" with a voluntary standard, the Commission should compare the compliance rate of the standard to that expected with a mandatory rule. Where the relevant provisions of the proposed mandatory standard and the adopted and implemented voluntary standard are materially the same, and the mandatory rule would achieve a higher degree of compliance, it may supersede the voluntary standard (if the Commission can make the other required statutory findings). Two factors provide substantive content to this comparative analysis: the extent to which the unreasonable risk of injury will be different, if at all, under a voluntary standard and a mandatory rule; and the comparative speed with which a voluntary standard or a rule will reduce this risk.

We begin with an examination of the Commission's past application of the "substantial compliance" finding.

^{3/} See also House Rep. 101-567, p. 19 (June 28, 1990) (referring to the Commission's deferral to voluntary standards "in the exercise of its informed discretion").

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(i) Past Applications of the "Substantial Compliance" Test.

The Commission has faced the question of "substantial compliance" on several occasions, principally with respect to toy chests, chain saws, and fireworks. The issue (or a closely related issue) has arisen more peripherally with respect to hair dryers, video games, and space heaters.

Toy chests. In 1982, the Commission issued an ANPR concerning a strangulation risk that certain toy chests with hinged lids presented to children. The Commission published a proposed rule setting performance standards for lid supports on March 17, 1983. 48 Fed. Reg. 11,289. The proposed rule was similar to an existing voluntary standard. Although the voluntary standard itself was adequate, the Commission initially did not have evidence that there would be "substantial compliance" with the standard.

[T]he Commission has not as yet received sufficient documentation to indicate that substantial compliance can be expected. If the number and relative size of the manufacturers who responded to TMA's and ASTM's inquiries about the standard is any indication of expected compliance, the extent of compliance might be only about 50 percent of all toy chests produced. If this should be the case, or even if the percent were somewhat higher, the degree of compliance with the voluntary standard would be too small to eliminate or adequately reduce the strangulation risk.

Id. at 11295 (emphasis added). The Commission thus focused on the extent to which compliance with a voluntary standard would eliminate or adequately reduce risk (although it did not state how it measured or defined "adequately reduce").

The staff then recommended that the Commission issue a final rule. In an August 3, 1983, memorandum, OGC raised questions about the evidence that "substantial compliance" with the voluntary standard was unlikely and stated that we were "unable to advise the Commission that it is likely that this rule, if issued at this time, would be upheld by a court on judicial review." Memorandum from H. Ewell through S. Lemberg, M. Katz, and S. Dunn to the Commission, p. 7 (Aug. 3, 1983).

At the Commission's August 10, 1983 meeting that followed, the staff continued to urge adoption of the final rule, but the Commission instead directed the staff to compile "updated information on possible industry compliance with the voluntary standard." Minutes of Commission Meeting, p. 2 (Aug. 10, 1983).

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The staff immediately undertook to assemble this evidence, with the results reported in an August 16, 1983, memorandum: "[W]e conclude that almost all toy chests with hinged lids produced in 1983 will be equipped with lid support devices of types that address the hazard." Memorandum from W. Hobby to the Commission, p. 2 (Aug. 16, 1983) (emphasis added). Based on this new evidence, the Commission then voted 3-2 to withdraw the proposed mandatory rule. Minutes of Commission Meeting (Oct. 15, 1983).

In a statement accompanying her vote in favor of the withdrawal, Chairman Steorts cited the fact that "[m]anufacturers have told our staff that they expect to be in full compliance with this voluntary standard for all future production. In fact, they claim that 98% of production this year has been in compliance." Statement of Nancy Harvey Steorts (Aug. 17, 1983) (emphasis added).

Chain Saws. At the outset of the Commission's examination in the early 1980's of a possible chain saw regulation, there was no effective voluntary standard, although the Commission expected industry to propose one by the end of 1981. In that context, OGC provided the following legal advice regarding the impact that such a voluntary standard could have on a rulemaking proceeding:

When these requirements [referring to CPSA sections 7, 8 and 9] are viewed in light of the situation concerning chain saws, in which the industry is expected to submit a voluntary standard to the Commission by December 15, 1981, it becomes apparent that before any mandatory standard can be proposed, the industry standard will have to be evaluated and findings made as to its expected potential injury reduction, in comparison to the expected results that could be achieved by a mandatory standard.

Memorandum from H. Ewell through S. Lemberg and M. Freeston to C. Blechschmidt, p. 2 (Nov. 5, 1981) (emphasis added). Thus, this office articulated a standard requiring a comparison of the effect that the voluntary standard and the mandatory standard would have in reducing injuries.

Several years later, in the July 1985 briefing package recommending termination of the chain saw rulemaking process, the staff reported on the level of conformance expected with the new voluntary standard.

EC also provided a memorandum on the expected conformance by manufacturers to the chain saw standard. They indicated that all gasoline powered chain saws sold in the U.S. are expected to conform to the kickback standard. Manufacturers who are members of

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the ANSI B175 committee and who voted for the standard account for over 90 percent of the chain saws shipped in the U.S. Additionally, EC reported that several small manufacturers who are not members of the ANSI Committee indicated they already conformed or intended to conform with the standard.

Briefing Package on Termination of the Proceeding to Develop a Consumer Product Safety Rule for Chain Saws, p. 4 (July 1985) (emphasis added).

In a contemporaneous legal memorandum, OGC characterized the staff's evidence as indicating there would be "virtually complete adherence" to the voluntary standard. Memorandum from D. Levinson, S. Lemberg, H. Ewell to the Commission, p. 1 (July 26, 1985). Similarly, at the Commission meeting to consider the staff's termination recommendation, Chairman Scanlon characterized the facts as indicating that there would be "close to 100 percent conformance" with the standard. Commission Meeting Regarding Chain Saws, p. 2 (Aug. 7, 1985). The subsequent Federal Register notice announcing termination of the rulemaking proceeding stated that the Commission had concluded that the voluntary standard would be "universally adopted" by the industry and, in a later passage, that "virtually all" chain saws would conform to the voluntary standard. 50 Fed. Reg. 35241, 35243 (Aug. 30, 1985). Two years later, the staff reported the results of its monitoring effort, in which it discovered that "all known manufacturers" were complying with the standard. Memorandum from D. Noble to the Commission, p. 5 (Nov. 6, 1987).

Like the toy chest proceeding, the chain saw rulemaking ended because the Commission found that all or virtually all of the products would conform to an effective voluntary standard.

Unvented Space Heaters. In 1984, the Commission revoked an existing rule that required oxygen depletion safety shutoff systems for unvented gas-fired space heaters. 49 Fed. Reg. 46,108 (Nov. 23, 1984). The Commission acted pursuant to Section 9(h) of the CPSA, which permits revocation only if the Commission "determines that the rule is not reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product."^{4/} Thus, although this proceeding did not implicate the term "substantial compliance," it concerned a closely related issue: When is a rule nevertheless necessary where a voluntary standard exists?

During the proceeding, the staff obtained evidence that compliance with the voluntary standard would remain high even if the mandatory standard were revoked. The staff and Commissioners

^{4/} Section 9(h) was part of the original 1972 legislation.

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essentially compared the level of compliance with the mandatory standard to the level of compliance expected with the voluntary standard. The Federal Register notice stated, "Information received by the Commission shows the level of compliance with a voluntary standard that addresses the risk to be very high, and is likely to continue in the future, even if the [mandatory] standard is revoked." Id. (emphasis added).

As early as 1982, the staff had concluded that "it is very likely that all unvented gas space heaters, intended for residential use and manufactured or imported in 1983, will be ODS-equipped." Memorandum from D. Noble to the Commission, p. 7 (Jan. 19, 1983) (reporting on a 1982 memo from EC). Later, in responding to questions from Commissioner Armstrong, who had reservations about revoking the standard, the staff said, "There is a very high degree of compliance with the ANSI voluntary standard for unvented gas space heaters Further, the staff can foresee no reason to expect the degree of compliance with the ANSI standard to decline should the Commission decide to revoke its standard." Memorandum from R. Medford to the Commission, p. 6 (Aug. 9, 1984). In concluding that the rule was not necessary, the staff thus compared the rates of compliance with the voluntary and mandatory standards. No change was expected with revocation of the mandatory standard.

Voting to revoke the standard, Commissioner Zagoria said, "I favor revocation because the industry has now developed a voluntary standard that is more stringent than the CPSC mandatory standard and equally likely to be adhered to by industry" Statement of Commissioner Sam Zagoria Regarding Unvented Gas Space Heaters (May 31, 1983) (emphasis added). Commissioner Scanlon issued a similar statement: "[T]he voluntary standard will be as effective as the mandatory standard It follows that the mandatory standard is not reasonably necessary to insure the safety of this particular consumer product." Statement of Commissioner Terrence M. Scanlon, p. 3 (May 26, 1983) (emphasis added).

Hair Dryers. Several years ago, the Commission was petitioned to issue a rule requiring immersion-detection circuit interrupters for hand-held hair dryers. In a January 9, 1990, memorandum to the Commission, OGC discussed pertinent legal issues, including the impact of a possible voluntary standard that was under consideration.

[I]t appears that "substantial compliance" is something more than the fact that "substantial industry wide production . . . has begun." The staff estimates that there is 80-90 percent compliance with the current voluntary UL standard. The legislative history does not specify any particular percentage of compliance that must be considered "substantial," and there are no

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cases interpreting this provision. However, we believe that it can be argued cogently that the Commission has the discretion to conclude that even 90 percent compliance is not "substantial compliance" for a product of this type that presents a risk of electrocution of children. If so, the likelihood that the UL standard will be amended to provide for full immersion protection would not prevent the Commission from issuing a valid final rule, if the current estimates of compliance with the UL standard do not go up substantially.

Memorandum from H. Ewell, S. Lemberg and S. Birenbaum to the Commission, pp. 8-9 (Jan. 9, 1990) (footnotes omitted; emphasis added). Thus, OGC specifically advised against reliance on a test based on a fixed percentage threshold.

On February 7, 1990, the Commission denied the petition, but apparently did not rely on the existence of the voluntary standard. See Letter from S. Dunn to D. Snow (Petitioner) (July 18, 1990).

Video Games. In 1992, the Commission exempted video games from its safety regulations applicable to electric toys and other electric articles for use by children. 57 Fed. Reg. 46,349 (Oct. 8, 1992). The Commission considered an alternative approach in which it would simply have amended its existing mandatory standard to make it essentially identical with the existing UL voluntary standard. However, the Commission concluded:

This would not be a feasible or desirable alternative for two reasons. First, the Commission is prohibited by statute from issuing a mandatory standard for a product when there is an adequate applicable voluntary standard for the product and there is substantial compliance with such voluntary standard. [Cite omitted]. This appears to be the situation with respect to video games and UL 961.

Id. at 46,353. The record does not set forth the test the Commission employed in arriving at this conclusion.

Reloadable Shell Fireworks. In the early 1990's, the Commission was considering whether to ban reloadable shell fireworks devices with shells larger than 1.75 inches. However, because a voluntary standard existed, it was necessary to consider its effect.

The staff determined that 50% to 75% of fireworks importers were complying with the voluntary ban, with the eventual compliance rate anticipated to be 80% to 90%. Memorandum from J. Rogers through various persons to the Commission, p. 10 (Dec.

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5, 1990). However, the staff feared that with a noncompliance rate of 10% to 20%, the complying manufacturers would face competitive pressures to reduce the level of their compliance, and the overall rate would slip. Id. Moreover, the staff concluded, "[W]ithout a Commission ban, some firms will continue to import large reloadable shells. If this happens, additional injuries could be expected to occur." Id.

The Commission voted 2-1 on January 16, 1991, to publish a notice of proposed rulemaking. Minutes of Commission Meeting (Jan. 16, 1991). Chairman Jones-Smith, who voted in favor, gave as one reason the fact that "supplemental information provided by the staff indicates that there may not be sufficient compliance with the voluntary standards." Statement of Chairman Jacqueline Jones-Smith (Jan. 16, 1991). Commissioner Dawson dissented, but in so doing, she did not rely on a percentage test, but rather made two comparisons:

The central argument against deferring to the non-government standard seems to be that staff fears there may be a conformance problem. Industry expects a conformance rate of 80-90 per cent with a certification program to enhance conformance. Given the Commission's difficulty in enforcing fireworks regulations already on the books, this conformance rate seems fairly high. Staff could not provide an estimate of how many more injuries would be prevented given the difference in the compliance rates of 80-90 per cent for a voluntary standard and an estimated 95 per cent rate for a mandatory rule.

Statement of Commissioner Carol G. Dawson (Jan. 16, 1991).

Thus, Commissioner Dawson first considered whether this fireworks rule would be any more effective than other fireworks rules. Second, she considered whether the rule could be expected to make a difference in the death and injury rate.^{5/}

^{5/}Commissioner Dawson had additional legal questions after the vote, which OGC answered in a June 13, 1991, memorandum. We concluded in that memorandum that the voluntary standard had not actually been implemented, so it was not of a type that required the Commission to consider its substantive adequacy and compliance rate. Memorandum from P. Pollitzer, S. Lemberg and C. Erhardt, p. 5 (June 13, 1991). (We opined, however, that if the Commission were to reach those questions, the staff had presented sufficient evidence for the Commission to conclude that substantial compliance with the standard was not likely. We relied on the staff's findings that imports of noncomplying products would continue, thus preventing an adequate reduction in the risk of injury. Id. at n.7.)

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The Commission ultimately determined that the voluntary standard had not been implemented, so it was not required to make any final findings regarding "substantial compliance." 16 C.F.R. § 1500.17(a)(11)(ii)(B).

Multiple-Tube Mine and Shell Fireworks. Most recently, in 1996, the Commission promulgated a regulation regarding these fireworks devices. It was necessary to consider the impact of an existing voluntary standard on the rulemaking process. OGC stated:

No specific number or percentage determines "substantial compliance." According to the legislative history, the Commission should consider whether compliance is sufficient to eliminate or adequately reduce an unreasonable risk "in a timely fashion." [Cite omitted]. Further, compliance should be measured by the number of complying products, rather than by the number of complying manufacturers. [Cite omitted].

Memorandum from H. Ewell, S. Lemberg, and E. Rubel to the Commission, p. 3, n.2 (Feb. 9, 1996).

The staff recommended against reliance on the voluntary standard because it thought substantial compliance was unlikely. OGC summarized the evidence and concurred:

CPSC's compliance testing indicates that, despite the voluntary standard, devices still tip over when functioning. In fiscal year 1994, all 24 samples of imported devices tested for the Commission's routine compliance program tipped over while functioning on 2" M-D foam, and 4 tipped over on grass. Further, 1 of 8 samples of domestic devices tested that fiscal year tipped over while functioning on 2" M-D foam. In fiscal year 1995, 22 of 27 imported samples tested tipped over. Of the 22, 13 tipped over only on 2" M-D foam, 8 tipped over on both 2" M-D foam and grass, and 1 tipped over only on grass. Of the 5 domestic samples tested that fiscal year, 1 tipped over (on grass). These data would support a Commission finding, required to issue the rule, that there is not likely to be substantial compliance with the voluntary standard.

Id. at 4. See also Memorandum from M. Babich and R. Medford to the Commission, p. 7 (Jan. 23, 1996) (setting forth evidence of noncompliance).

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In announcing the final rule, the Commission stated that the voluntary standard was not substantively adequate and that, even if it were, compliance with it was not substantial (citing the evidence set forth above). 61 Fed. Reg. 13,084, 13,092 (March 26, 1996).

Conclusions. This review of past Commission actions discloses the following:

First, we have discovered no instance in which either the Commission or individual Commissioners have applied or endorsed a test based on a specific percentage threshold. OGC has never advised that "substantial compliance" is measured with such a test; in fact, we have consistently advised just the opposite.

Second, where it was clear that "virtually all" products would comply or that very few were in compliance, neither the Commission nor OGC elaborated in any detail the particular test being applied. In instances where the test was articulated, it seems generally to have focused on the extent to which the injury and/or compliance rate would be different with a mandatory standard.

(ii) The Statutory Language.

We turn now to the language of the statute. However, it nowhere defines "substantial compliance," nor does it set benchmarks for identifying when compliance with a voluntary standard is "substantial."

Without further guidance from the legislative history or overall statutory scheme, there could be several theoretically plausible ways to interpret the term "substantial compliance." For example:

* "Substantial compliance" might be measured by a percentage test. If so, would it be measured by the percentage of complying products or of complying manufacturers (two numbers that will likely never be the same) or is yet some other percentage applicable? If a percentage test applies, what is the appropriate percentage and how is it selected? (As noted above, this test has not been applied in the past.)

* "Substantial compliance" might be measured by reference to the risk arising from the remaining noncomplying products or manufacturers. If so, is "substantial compliance" to be found whenever that risk could be reduced, or should a cost/benefit calculation be done with respect to remaining risk?

* "Substantial compliance" might be measured by comparing the compliance rate of the voluntary standard to that anticipated for the competing mandatory standard. Where the mandatory

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standard would yield higher and/or quicker compliance, and thus greater risk reduction, it could be said that there is not "substantial compliance" with the voluntary standard.

The "plain language" of the statute (viewed narrowly, rather than structurally, as discussed below) simply does not identify the specific level of compliance at which a voluntary standard trumps a mandatory standard.

There are no cases construing the term "substantial compliance" in our statutes, and a review of cases interpreting similar language sheds little light. The Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") provides that in order for a party to prevail in an action to recover the costs of responding to a release or threat of release of hazardous materials from a site, the costs must be consistent with the national contingency plan ("NCP") also required by CERCLA. 42 U.S.C. §§ 9605(a), 9607(a)(4)(B). Courts generally hold that a response action can be "consistent" with the NCP if there is substantial, rather than strict, compliance with the NCP. In this context, substantial compliance has been interpreted as requiring, at a minimum, that a "CERCLA-quality cleanup" resulted from the response actions. See, e.g., Con-Tech Sales Defined Benefit Trust v. Cockerham, (E.D. Pa. 1991).^{5/} This body of CERCLA law is not useful.

Some courts hold that the issuer of a letter of credit may honor a demand for payment that is in substantial compliance with the terms of the credit. In this context, substantial compliance permits insignificant variance between the letter of credit requirements and the documents submitted. See, e.g., First Arlington Nat'l Bank v. Stathis, 90 Ill. App. 3d 802 (1980).^{2/} Substituting one vague term -- "insignificant variance" -- for another -- "substantial compliance" -- does not advance the analysis here.

Another example of the term "substantial compliance" involves a regulation issued by the Food and Drug Administration ("FDA")^{3/} under the Nutritional Labeling and Education Act of

^{5/} See generally, Annotation, Application Of Requirement In § 107(a) Of [CERCLA] That Private Cost-Recovery Actions Be Consistent With [NCP], A.L.R. FED 562 (1992).

^{2/} See generally Annotation, What Constitutes Compliance Of Documents Presented With Terms Of Letter Of Credit So As To Require Honor Of Draft Under UCC § 5-114, 8 A.L.R. 5th 463 (1992).

^{3/} 21 C.F.R. § 101.43.

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1990 ("NLEA").^{2/} The NLEA established voluntary guidelines for retail food stores to provide consumers with nutritional information about raw produce and fish. The NLEA further provides that if the FDA finds that such stores overall are not in "substantial compliance" with the guidelines, the FDA must issue mandatory food labeling regulations.

Unlike our statutes, the NLEA directed FDA to promulgate a regulation defining "substantial compliance."^{10/} FDA selected a percentage threshold test. Its regulation provides that there is industry-wide substantial compliance under the NLEA if at least 60% of establishments evaluated were in compliance. 21 C.F.R. § 101.43(c). The D.C. Circuit upheld this regulation under the lenient "arbitrary and capricious" standard of review. Arent v. Shalala, 70 F.3d 610 (D.C. Cir. 1995).

FDA's percentage test cannot be transplanted to our statutes. In other words, even if a percentage threshold test were applicable in our statutes, the 60% threshold that FDA used would not apply. This is because FDA's test is based on the number of establishments in compliance, and this particular measure is foreclosed to the Commission by pertinent legislative history, discussed below, which says that compliance is measured by number of products, not number of manufacturers.

It is impossible to translate FDA's test into a percentage test for products themselves. The court noted that the top 18% of U.S. food stores accounted for 81.5% of sales, and that the smallest 42.6% accounted for only 2.7% of sales. 70 F.3d at 617. Accordingly, if FDA's test were to be met, compliance measured by sales would necessarily exceed 97% if the largest-selling stores were combined to reach 60% (100% minus 2.7% of sales for the smallest 42.6% of stores). On the other hand, if only the lowest-selling stores were combined to reach the 60% level, compliance (measured by sales) could be 18.5% or below (100% minus 81.5% of sales for the top-selling 18% of stores). In reality, of course, compliance undoubtedly was scattered across stores of all sizes, underscoring the impossibility of translating FDA's test here.

^{2/} 21 U.S.C. §§ 321, 337, 343, 343-1, 345, 371.

^{10/} The NLEA stated that "[t]he regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether there was substantial compliance with the voluntary guidelines." 21 U.S.C. § 343(q)(4)(B)(ii).

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These cases provide little or no guidance to our interpretive puzzle.

(iii) The Legislative History.

There is little legislative history regarding the meaning of "substantial compliance." The 1981 amendments to our statutes were in the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35. The 1990 amendments were in the Consumer Product Safety Improvement Act of 1990, Pub. L. 101-608, 104 Stat. 3110. For each piece of legislation, there are three reports -- the House report, the Senate report, and the House Conference report. In addition, there was Congressional debate. As will be seen, there is no discussion of "substantial compliance" in the 1990 legislative history, so the 1981 history is most on point. However, by 1990, Congress could look back on nearly a decade of the Commission's deferral to voluntary standards, and its reaction to that history may be of some assistance. We will discuss the 1981 legislative history first, followed by the 1990 legislative history.

1981 Legislative History

The 1981 Senate report, the 1981 House report and the 1981 House Conference report all discuss "substantial compliance." (We have located no discussion of "substantial compliance" in the Congressional debate).

Senate Report No. 97-102. With respect to the meaning of "substantial compliance," the Senate Report states as follows:

In evaluating whether there will be substantial compliance with a voluntary consumer product safety standard, the Commission should determine whether or not there will be sufficient compliance to eliminate or adequately reduce an unreasonable risk of injury in a timely fashion. In most situations, compliance should be measured in terms of the number of complying consumer products rather than in terms of the number of complying manufacturers.

Senate Report No. 97-102, p. 14 (May 15, 1981) (emphasis added).

House Report No. 97-158. There are three references to "substantial compliance" in this report. First, with respect to language very similar to that now in Section 7(b)(1) of the CPSA, the House Budget Committee wrote:

[T]he agency must determine if: (1) compliance with the standard is likely to result in the elimination or adequate reduction of the risk of injury; and (2) there will be substantial compliance

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with the standard. If a . . . standard does not meet either part of this two-pronged test, then the standard is inadequate. The Committee has chosen a flexible standard of "likely to result in the elimination or adequate reduction" of a risk of injury because these determinations cannot be reduced to a simple formula. Instead, the agency must consider whether the submitted standard will reduce the risk to a sufficient extent that consumers will no longer be faced with an unreasonable risk of injury. In determining whether there will be substantial compliance with a submitted standard, the Committee intends that compliance be measured in terms of the number of complying products rather than in terms of complying manufacturers.

House Report No. 97-158, p. 11 (June 19, 1981).

Later, referring to the "substantial compliance" language added to Section 9 of the CPSA, the Committee stated:

In evaluating whether a voluntary standard is likely to eliminate or reduce adequately a risk of injury, the agency must consider whether the risk will be reduced to a sufficient extent that consumers will no longer be exposed to an unreasonable risk of injury.^{11/} In evaluating whether there will be substantial compliance with a voluntary standard, the agency should measure compliance in terms of the number of complying consumer products rather than in terms of complying manufacturers.

Id. at 17 [footnote added].

Finally, the House bill had a provision that would have given adequate voluntary standards preemptive effect over nonfederal standards. This language ultimately was dropped in conference, and the House legislative history mentions

^{11/} The Committee did not define "unreasonable risk of injury." However, by 1981, this term had a well-established meaning. The 1972 legislative history had defined "unreasonable hazard" as "one which can be prevented or reduced without affecting the product's utility, cost or availability; or one which the effect on the product's utility, cost or availability is outweighed by the need to protect the public from the hazard associated with the product." H.R. Rep. No. 92-1153 (1972) at 33. See Southland Mower Co. v. Consumer Product Safety Commission, 619 F.2d 499, 509 n.21 (5th Cir. 1980) (quoting House Committee Report). Since 1972, courts had consistently applied this analysis (see cases cited in Southland, at 509).

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"substantial compliance" without explaining it. See id. at 39-40.

House Conference Report. The conference report accompanying the resulting legislation has two references to "substantial compliance." First, referring to use of the term in Section 7 of the CPSA, the report says:

In evaluating whether there will be substantial compliance with a voluntary consumer product safety standard, the Commission should determine whether or not there will be sufficient compliance to eliminate or adequately reduce an unreasonable risk of injury in a timely fashion. In most situations, compliance should be measured in terms of the number of complying consumer products rather than in terms of the number of complying manufacturers.

H. Conf. Rep. No. 97-208, 97th Cong., 1st Sess. 871, reprinted in 1981 U.S. Code Cong. & Admin. News 1010, 1233 (emphasis added).

Similarly, the following paragraph was written of the use of the term "substantial compliance" in Section 9 of the CPSA:

In determining whether or not it is likely that there will be substantial compliance with such voluntary consumer product safety standard, the Commission should determine whether or not there will be sufficient compliance to eliminate or adequately reduce an unreasonable risk of injury in a timely fashion. Therefore, compliance generally should be measured in terms of the number of complying products rather than in terms of complying manufacturers.

Id. at 873, 1981 USCCAN at 1235 (emphasis added).

These 1981 passages (particularly those from the Conference report) suggest that "substantial compliance" may be defined by reference to two considerations: (i) the extent to which compliance with the voluntary standard would eliminate or "adequately reduce" the "unreasonable risk" associated with the product; and (ii) whether this reduction would occur in a "timely fashion." (The history also makes clear that "substantial compliance" generally is measured by reference to products, not manufacturers.) However, the legislative history does not describe how these considerations are measured.

One might measure the first factor -- "adequately reduce" -- with a cost/benefit analysis. Under this measure, if it would be cost effective to reduce or eliminate the increment of risk remaining between a voluntary standard and a mandatory standard that would be more widely implemented, there would be no

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substantial compliance with a voluntary standard. However, this test would largely duplicate the separate statutory requirement that "the benefits expected from the regulation bear a reasonable relationship to its costs." CPSA § 9(f)(3)(E); FHSA § 3(i)(2)(B). Congress added the separate requirement for a reasonable-relationship-of-costs-to-benefits finding to our statutes in 1981, along with the "substantial compliance" requirement. The legislative history very clearly treats these separately and states that the "reasonable relationship" test (which applies also to rulemakings that do not implicate voluntary standards) was intended to codify "the cost-benefit test articulated by the court" in Southland, 619 F.2d 499 (discussed earlier). H. Conf. Rep. No. 97-208, supra, 1981 USCCAN at 1237. The history contains no similar statement regarding the "substantial compliance" finding, as would be expected if Congress had intended the term to have the same meaning. Moreover, it is fundamental that, if possible, a statute should be construed "so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant" 2A Sutherland Statutory Construction Sec. 46.06, pp. 119-120 (5th Ed. 1992). Thus, any view that the Commission should measure the "adequate reduction" of injury risk (as this consideration relates to "substantial compliance") with a cost/benefit analysis rests on shaky grounds.^{12/}

Neither the statute nor the legislative history elaborate on the meaning of "in a timely fashion" -- the second factor.

^{12/} Any argument that a cost/benefit analysis applies to the "substantial compliance" determination would stem from the legislative history's occasional use of the terms "adequately reduce" and "unreasonable risk of injury" in its discussion of "substantial compliance." See Senate Report 97-102 at 14; H. Conf. Rep. 97-208 at 873. "Unreasonable risk of injury" often connotes use of a cost/benefit analysis. See note 11. However, our statutes do not use these terms in connection with the "substantial compliance" requirement, whereas they do refer to the adequate reduction of injury risk in connection with the requirement that the voluntary standard be substantively adequate. Congress thus was perfectly capable of using the "adequately reduce" language in our statutes where it wished. See, e.g., CPSA §§ 7(b)(1), 9(b)(1)-(2), 9(f)(3)(D, F), and 9(i). This discriminatory use of terminology in our statutes further indicates that "substantial compliance" likely is not determined by a cost/benefit approach. Southland, 619 F.2d 499 (discussed earlier).

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Although the 1981 legislative history falls somewhat short of affirmatively establishing a test for "substantial compliance," it seems more clear on what the test is not: There is no support for a simplistic test declaring compliance above a certain percentage threshold as "substantial." Instead, the history supports a more nuanced analysis focusing on timely and effective risk reduction.

1990 Legislative History

There is no discussion of "substantial compliance" in any of the reports or the debate accompanying the 1990 amendments. However, certain passages in this legislative history do speak broadly about the role Congress (or at least certain key members) saw for voluntary standards.

Judging from the legislative history, in 1990 Congress perceived that the Commission had gone too far in relying on voluntary standards after the 1981 amendments, and particularly had erred in deferring to voluntary standards that were not yet adopted or implemented. Thus, the thrust of the 1990 amendments, insofar as they pertained to voluntary standards, was to define more specifically when a voluntary standard would be deemed to have been implemented.

For example:

* The 1990 Senate Report says, "[T]he CPSC requires that the CPSC defer to voluntary standards in certain circumstances. Suggestions have been made that this requirement has been used to thwart compliance and enforcement activities of the CPSC, which is clearly contrary to congressional intent." S. Rep. No. 101-37, p. 2 (May 25, 1989) (emphasis added).

* Later, that same Report states:

The Committee consistently has received testimony and comments regarding the voluntary standards process since the provisions were enacted in 1981. . . . [T]he Committee is aware that the CPSC at times has not been responsive to concerns that voluntary standards development has been inadequate or too slow. In fact, it has been suggested that the CPSC may seek to utilize the deferral to voluntary standards . . . to justify inaction or delay with regard to product risks. This is clearly contrary to the intent of the 1981 amendments. The development of voluntary standards should proceed as expeditiously as possible, with aggressive development of standards adequate to address the risks of injury.

Id. at 7 (emphasis added).

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* Still later, the Senate Report says:

The Committee reaffirms its belief that voluntary safety standards can play an important role in protecting consumers. CPSC deference to voluntary standards permits the CPSC to save scarce resources and can permit safety problems to be addressed in a more expeditious manner than might otherwise occur, thereby saving lives and preventing injuries. Such deferral authority, however, was not intended to become an excuse for inaction or delay on the part of the CPSC, including delay in issuing ANPRs where such issuance is appropriate.

Id. at 9 (emphasis added).

On the other hand, we have found no evidence in the legislative history (and certainly the statute was not so amended) to suggest that there was any fundamental change in the legal requirements applicable to the Commission's deferral to voluntary standards. In fact, the member who (with others) had introduced the original 1990 House legislation, said this about the final legislation:

I want to emphasize that it is not the intent of the conference report to discourage CPSC reliance on voluntary standards. Voluntary standards can usually be developed much more rapidly than can consumer product safety rules, and be just as effective in addressing potential product safety hazards. I believe that by specifying the procedures that CPSC should use to defer to voluntary standards, we will actually encourage more such deferral.

Remarks of Cong. Ritter (ranking Republican on the Energy and Commerce Committee subcommittee with responsibility for the legislation), 136 Cong. Rec. H11906-02, H11907 (Oct. 23, 1990) (emphasis added). (Note that Cong. Ritter endorsed deferral to voluntary standards on the assumption they would be "just as effective" as rules.)

Conclusions

There is risk in placing too much weight on legislative history. The only law is the statute itself. Congress does not adopt legislative reports, nor does it endorse remarks by individual members. All these cautions are multiplied when seeking to plumb the 1990 legislative history for meaning regarding the 1981 legislation.

Nevertheless, we believe the legislative history generally supports a few key principles. First, "substantial compliance"

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may be defined by reference to the scope and pace of risk reduction. Second, Congress never contemplated a test based on some percentage threshold. Finally, the 1990 legislative history (which must be given only light weight with respect to the 1981 legislation) suggests that deferral to voluntary standards was not intended to weaken the Commission, but rather to preserve its resources and allow the same safety results to be achieved.

(iv) Structure of the Statute.

The overarching policy evident in the rulemaking provisions of the CPSA and FHSA (and the companion provision FFA) suggests a meaningful analysis for "substantial compliance." These provisions make clear that voluntary standards are preferred over rules. See, e.g., FHSA §§ 3(f)(5); 3(f)(6); 3(g)(2); 3(g)(3); 3(i)(2); 3(j).^{13/} The statutory deference to voluntary standards indicates that Congress viewed them as substitutes for mandatory rules. Where fully effective voluntary standards exist, no rules can issue. In taking this approach, Congress ensured that the Commission would not squander resources where they would have no effect.

However, there are two important caveats to the statute's general deference to voluntary standards. If a voluntary standard is to substitute for a rule, it must first be substantively adequate and, second, manufacturers must follow it. Section 3(i)(2)(A). These are logical caveats, for how would consumer safety be guarded by deferring to an inadequate standard or by deferring to a standard that was not followed?

Consequently, it is our opinion that "substantial compliance" properly is measured by a comparison of the mandatory and voluntary standards, rather than by an absolute measurement of compliance with the voluntary standard.^{14/} The compliance level expected with a mandatory rule should be compared to the compliance level expected or experienced with the voluntary standard. Where there is some reasonable basis for concluding that a mandatory rule would achieve a higher degree of

^{13/} This emphasis on the primacy of voluntary standards is mirrored in the CPSA and FFA. See, e.g., CPSA §§ 5(a); 7(b); 9(b)(2); 9(f)(3); 9(i); FFA § 4.

^{14/} Under this comparative test, the absolute percentage of complying products is not determinative (although assembling this information may, in a particular case, be useful in making the comparative analysis). Comparative measurements are common in everyday life, so it is no surprise for this type of measurement to find its way into law. To use a simple illustration, parents not only measure their children with a yardstick, but also by comparing their growth to the height of their mother or father.

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compliance, i.e., a greater reduction of injury, it may supersede the voluntary standard.

As noted, the legislative history assists in fleshing out this comparative test by suggesting that "substantial compliance" is a surrogate for the extent and pace of injury reduction. Accordingly, two specific criteria should be measured comparatively in assessing "substantial compliance": the reduction in the risk (the legislative history's "eliminate or adequately reduce" language) and the speed with which this reduction will occur (the "in a timely fashion" language). In a particular case, additional factors may also be pertinent, but these two are central.

We recognize that difficult issues of proof may arise in determining whether "substantial compliance" exists. However, this is true of all rulemaking findings. In any event, this difficulty is mitigated here: As we stated at the outset, the cryptic generality of the statutory language, which the legislative history indicates was deliberate, leaves the Commission a generous degree of discretion in making its "substantial compliance" finding.

We emphasize that the Commission need not calculate the comparative compliance levels with scientific precision and reduce each to a specific percentage number. Only rarely, if at all, would this be possible, since the comparison is between something that may or may not be reasonably known (the extent of present or future compliance with the voluntary standard) and something that is necessarily subject to greater uncertainty (the extent of compliance with a nonexistent mandatory standard). The inquiry is a qualitative assessment of the relative efficacies of the voluntary and mandatory standards in achieving timely injury reduction. The extent and nature of the evidence bearing on this inquiry doubtless will continue to vary from case to case.

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